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# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,

No. MDL 15-02641-PHX DGC

### **ORDER**

This multidistrict litigation ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard has filed motions to exclude the opinions of Drs. Thomas Kinney, Anne Christine Roberts, and Sanjeeva Kalva. Doc. 7296. The motion is fully briefed, and the Court heard arguments on December 15, 2017. The Court will grant the motion in part.

## I. Background.

Each Plaintiff in this MDL received an implant of a Bard IVC filter and claims that the filter is defective and has caused serious injury or death. Plaintiffs allege that Bard filters tilt, perforate the IVC, or fracture and migrate to neighboring organs. Plaintiffs claim that Bard filters are more dangerous than other IVC filters, and that Bard failed to warn about the higher risks. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1. Bard disputes Plaintiffs' allegations,

contending that complication rates for Bard filters are comparable to those of other IVC filters, and that the medical community is aware of the risks associated with IVC filters.

The parties intend to use various expert witnesses at trial, including medical professionals. The doctors subject to the present motion are interventional radiologists whom Plaintiffs have identified as expert witnesses on various issues in this MDL. Defendants ask the Court to exclude four categories of opinions from these experts: (1) their reliance on expert reports of other doctors in forming their opinions; (2) their "summaries and editorials" concerning deposition testimony and a small percentage of the internal Bard documents produced in the litigation; (3) opinions about the "reasonable expectations" of physicians and how a "reasonable physician" would act upon receiving certain information regarding Bard filters; and (4) opinions about IVC filter engineering and the suitability of Bard's bench testing of its filters. *Id.* at 2-3. Plaintiffs oppose the motion. Doc. 7812. The Court will address each of Defendants' arguments.

## II. Legal Standard.

Under Rule 702, an expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). The proponent of expert testimony has the ultimate burden of showing, by a preponderance of the evidence, that the proposed testimony is admissible under Rule 702. See Lust v. Merrell Dow Pharm., Inc., 89 F.3d 594, 598 (9th Cir. 1996). The trial court acts as a gatekeeper to assure that expert testimony "both rests on a reliable foundation and is relevant to the task at hand." Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 597 (1993). Rule 702's requirements and the Court's gatekeeping role apply to all expert testimony, not just scientific testimony. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 147 (1999).

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#### III. Discussion.

## A. Reliance on Other Expert Reports and Bard Documents.

Without identifying any particular opinion or a specific portion of the doctors' expert report (*see* Doc. 7301), Defendants ask the Court to preclude the doctors from providing any testimony that relies on the report of another expert or on internal Bard documents. Defendants assert that these are not sources of information on which doctors normally would rely as required by Federal Rule of Evidence 703. The Court is not persuaded.

The rule for one expert's reliance on another expert's opinion has been well summarized by Judge Selna:

[E]xpert opinions may find a basis in part on what a different expert believes on the basis of expert knowledge not possessed by the first expert. Indeed, this is common in technical fields. For example, a physician may rely for a diagnosis on an x-ray taken by a radiologist, even though the physician is not an expert in radiology. There is no general requirement that the underlying expert testify as well. There are limits to this general rule, however. Where the soundness of the underlying expert judgment is in issue, the testifying expert cannot merely act as a conduit for the underlying expert's opinion. Moreover, more scrutiny will be given to an expert's reliance on the information or analysis of another expert where the other expert opinions were developed for the purpose of litigation.

In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prods. Liab. Litig., 978 F. Supp. 2d 1053, 1066 (C.D. Cal. 2013) (quotation marks, citation, and brackets omitted); see also E. Allen Reeves, Inc. v. Michael Graves & Assocs., Inc., No. 10-1393 (MAS), 2015 WL 105825, at \*5 (D.N.J. Jan. 7, 2015) ("An expert . . . may rely on the opinion of another expert in formulating his or her opinion."); Eaves v. United States, No. 4:07-CV-118-M, 2009 WL 3754176, at \*9 (W.D. Ky. Nov. 5, 2009) (denying motion to preclude expert testimony because experts may rely upon the opinions of other experts); Weinstein's Federal Evidence, § 703.04[3] (2017) (Rule 703 permits experts to rely on "[o]pinions of other experts") (citing cases). Thus, the Court does not agree with Defendants' assertion that some or all of the doctors' opinions must be excluded because

they cite, refer to, or even rely on the opinions of other experts in this litigation. The doctors will not be permitted to parrot the opinions of other experts or to vouch for those experts, but they can rely on opinions stated by other experts.

Nor can the Court conclude that the doctors' opinions should be excluded or limited because they rely on internal Bard documents. Those documents are factual evidence in this case, and experts clearly are permitted to take factual evidence into account. Rule 702 requires that experts base their testimony on sufficient facts and apply their expertise "to the facts of the case." Fed. R. Evid. 702(b), (d). Indeed, the first sentence of Rule 703 specifically states that "[a]n expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed." The Court cannot accept Defendants' suggestion that an expert cannot rely on a factual source unless the expert previously relied on that source in his or her medical practice. *See Weinstein's Federal Evidence* § 703.04[3] (experts may rely on interviews, reports prepared by third parties, clinical and other studies, business, financial, and accounting records, and general knowledge or experience) (citing cases).

The parties disagree on the extent to which the doctors reviewed the factual material on which they rely. Defendants contend that the doctors relied largely on Dr. Kessler's summary of relevant documents and did not conduct their own independent review of Bard documents. Doc. 7296 at 6. Plaintiffs disagree, asserting that the doctors conducted a thorough evaluation of the documents supporting the opinions of the other experts. Doc. 7812 at 7-8. But even if the doctors did not review every relevant Bard document (Defendants do not identify any they overlooked) and relied to some extent on Dr. Kessler's extensive chronology and summary, the Court cannot conclude that this renders their opinions inadmissible. Their opinions clearly are based on their expertise as interventional radiologists, the doctor's testimony will be confined to their area of

<sup>&</sup>lt;sup>1</sup> In a footnote, Defendants ask that the doctors be precluded from using the schedules attached to their report during their testimony. Doc. 7296 at 5 n.1. The Court need not resolve this issue because Plaintiffs state that the doctors "will not refer to the schedules while testifying[.]" Doc. 7812 at 7 n.7.

expertise, and if Defendants believe the opinions are based on a slanted or inaccurate view of the facts, they certainly will be free to demonstrate that during cross examination.

Nor is the Court persuaded by Defendants' assertion that these experts cite less than 0.0028% of Bard's internal documents. The actual percentage of a party's documents relied on for trial is always exceedingly small, especially in these days of electronically stored information when the amount of available information greatly exceeds the amount of information that reasonably can be used in a trial.

#### **B.** Summaries and Editorials.

Defendants ask the Court to preclude the doctors from "quoting, summarizing, and offering editorials about deposition testimony and Bard's internal documents," asserting that such testimony would be unhelpful to the jury. Doc. 7296 at 7. Plaintiffs respond that the doctors "will not testify solely as 'summarizers' of documents. Instead, their proposed testimony about Bard's internal documents will provide a contextual and factual foundation for their opinions as interventional radiologists[.]" Doc. 7812 at 11.

Line drawing in the context of such generalized arguments is not possible, and Defendants identify no specific testimony that the Court should exclude. Defendants do cite to a few paragraphs in the doctors' 115-page expert report, but otherwise make no specific request regarding testimony to be excluded.

Experts on both sides of this case will be permitted to state opinions within their areas of expertise and to explain the factual, medical, technical, or scientific bases for those opinions. This testimony will be helpful to the jury and necessarily will require the experts to discuss some factual evidence. Experts will not be permitted to engage in lengthy factual narratives that are not necessary to the jury's understanding of their opinions, nor will they be permitted to gratuitously comment on factual evidence or present what are essentially lawyer arguments with regard to factual testimony. Rules 703 and 705 will apply to any expert's explanation of opinions. In short, the Court will seek to strike the proper balance at trial between (a) allowing experts to reasonably explain their opinions in a manner helpful to the jury and (b) avoiding unnecessary

factual recitation or argument. More detailed rulings are not possible at this stage of the proceeding. *See In re Actos Prods. Liab. Litig.*, No. 12-cv-00064, 2014 WL 120973, at \*10 (W.D. La. Jan. 10, 2014) ("The objection that testimony is 'narrative' is an objection as to form, foundation, or responsiveness, and must be presented at trial."); *In re Yasmin & YAZ Prods. Liab. Litig.*, MDL No. 2100, 2011 WL 6302287, at \*8 (S.D. Ill. Dec. 16, 2011) (noting that issues concerning narrative testimony should be "decided at trial in context specific situations").

## C. Opinions on Reasonable Expectations and Physicians.

Defendants ask the Court to exclude opinions as to what a physician reasonably expects to be told about the risks of IVC filters, or what a reasonable physician would do with certain adverse information about the devices. Doc. 7296 at 9-10; *see* Doc. 7301 ¶¶ 3, 7, 65-66, 73, 75-76, 182. Plaintiffs counter that the doctors are qualified to offer such opinions given their expertise in interventional radiology and use of IVC filters, and that the opinions have a reliable foundation. Doc. 7812 at 12-15.

Defendants challenge these opinions because "they are not grounded in any reliable source of authority, they have not been tested or peer reviewed, they have no known rate of error, they have not been published, and the physicians have not identified their view as generally accepted in the medical community." Doc. 7296 at 2-3, 9. But these factors are neither exclusive nor dispositive in a Rule 702 inquiry, see Daubert, 509 U.S. at 593-94, and "may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010) (quoting White v. Ford Motor Co., 312 F.3d 998, 1007 (9th Cir. 2002)). As the Supreme Court has explained, although some expert testimony "rests upon scientific foundations," in other cases "the relevant reliability concerns may focus upon personal knowledge or experience. *Daubert* makes clear that the factors it mentions do not constitute a definitive checklist or test." Kumho Tire, 526 U.S. at 150 (citations omitted; emphasis in original). The Ninth Circuit likewise holds that "[t]he Daubert factors (peer review, publication, potential error rate, etc.) simply are

not applicable to [testimony] whose reliability depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it." *United States v. Hankey*, 203 F.3d 1160, 1169 (9th Cir. 2000).

This holds true for much medical testimony. As the Ninth Circuit has noted, medicine "is not a science but a learned profession, deeply rooted in a number of sciences and charged with the obligation to apply them for man's benefit." *Primiano*, 598 F.3d at 565 (quotation marks and citation omitted). "Despite the importance of evidence-based medicine, much of medical decision-making relies on judgment – a process that is difficult to quantify or even to assess qualitatively." *Id.* (quotation marks and citation omitted). Thus, "a doctor's experience might be good reason to admit his testimony." *Id.* at 566 (citing *Dickenson v. Cardiac & Thoracic Surgery of E. Tenn.*, 388 F.3d 976, 982 (6th Cir. 2004); *Schneider v. Fried*, 320 F.3d 396, 406-07 (3d Cir. 2003)).

Defendants do not dispute that the doctors are highly qualified experts in interventional radiology and the use of IVC filters. In Defendants' own words, the doctors "are practicing interventional radiologists, members of radiological societies, reviewers for radiological journals, and authors of articles and presentations concerning the clinical use of IVC filters." Doc. 7296 at 2. Under Rule 702 and *Daubert*, expert testimony "is reliable if the knowledge underlying it has a reliable basis in the knowledge and experience of the relevant discipline." *Primiano*, 598 F.3d at 565 (citation omitted). The Court finds that the doctors' knowledge and experience in the field of interventional radiology and the use of IVC filters in patients form a sufficient foundation for their opinions.

In support of their argument that these experts cannot state opinions on what doctors "reasonably expect" to be told about the risks of IVC filters, or what a "reasonable physician" would do with certain adverse information about the devices, Defendants cite several cases. The Court is not persuaded, however, that the cases fully support Defendants' position.

The court in *In re Diet Drugs*, No. MDL 1203, 2000 WL 876900 (E.D. Pa. June 20, 2000), held that two doctors were not qualified to opine "about what all doctors generally consider in making prescription decisions." *Id.* at \*11. The basis for this conclusion is not entirely clear from the court's decision, but it appears that the court was not comfortable with the scope of the opinion – what "all doctors" think. The court did not address whether the doctors could opine on what information a reasonable physician in a particular specialty might find important.

In *In re Diet Drugs*, No. MDL 1203, 2001 WL 454586 (E.D. Pa. Feb. 1, 2001), the same judge, in the same proceeding, held that an FDA-expert physician was "not qualified to opine on what decisions would have been made by the numerous physicians who prescribed diet drugs had they been provided with different labeling information." *Id.* at \*18. The court explained: "Unlike opining about what physicians in general expect to see on a label, his surmising as to what physicians would do with different information is purely speculative and not based on scientific knowledge." *Id.* The court thus appeared to recognize that an expert could testify about what physicians in general expect to see on a label – testimony very similar to Plaintiffs' proposal that Drs. Kinney, Roberts, and Kalva testify about what interventional radiologists expect in medical product disclosures.

The third case cited by Defendants, *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531 (S.D.N.Y. 2004), relied on the *Diet Drugs* decisions to hold that a doctor could not testify that physicians would not have prescribed a particular drug if the manufacturer had made full disclosures. The court explained: "Unlike opining about what physicians in general expect to see on a label, his surmising as to what physicians would do with different information is purely speculative and not based on scientific knowledge." *Id.* at 557. Again, the court recognized that the expert could testify about what physicians in general expect to see on a label.

The Court cannot conclude from these cases that Drs. Kinney, Roberts, and Kalva should be precluded from testifying about disclosures that reasonable radiologists expect

to receive from manufacturers of IVC filters. Such testimony, if relevant, appears to be well within their expertise and experience, and the Court can identify no basis under Rule 702 for precluding it.

Whether the doctors should also be permitted to testify about what doctors would have done with additional information seems more problematic. Whether and when to use a particular product appears to be a more fact- and patient-specific decision, not amenable to broad generalizations. The propriety of testimony on this subject will depend heavily on the context and relevancy of the question. The Court will need to draw these lines during trial.

## D. Opinions on Engineering, Bench Testing, and Filter Performance.

Defendants note that the doctors render various opinions about filter engineering and the suitability of Bard's testing procedures. Defendants argue that the doctors are not qualified to render such opinions. Doc. 7296 at 13. The Court agrees in part.

Dr. Kinney received a master's degree in mechanical engineering in 1979 and accepted a job with a physician designing angioplasty balloons, vascular clams, and a cardioplagia jacket for use during open heart surgery. In 1983, Dr. Kinney entered medical school and continued to work with the cardioplagia jackets as part of his independent study. Since graduating from medical school, Dr. Kinney has not done any medical device design work, and he has never designed bench top testing. Doc. 7296 at 12 (citing record). Dr. Kinney has served as chair of data safety monitoring boards for clinical trials involving other IVC filters, and has published studies and review articles on IVC filters, including IVC design function. Doc. 7812 at 15-16 (citing record).

Drs. Roberts and Kalva are clinical physicians with no background in engineering or actual bench testing of medical devices. The doctors have studied IVC filters and have seen filter failures in their medical practices. Dr. Kalva has published studies on the function, use, and complications of IVC filters, and is involved in developing an undisclosed patent for an IVC filter design. *Id*.

Defendants assert that the doctors are not qualified to opine on a number of matters in their export report. The Court's task in ruling on this motion is complicated by the fact that Defendants cite specific paragraphs of the doctors' report that include both mechanical and medical opinions, and Plaintiffs' response does not address many of the paragraphs cited. For example, Defendants object to report paragraphs 115 (opining about how changing of the size of the diameter of the Bard filter impacted the radial force for the hook to engage the cava wall), 120 (opining about pressure gradient bench testing), 127 (opining about fatigue resistance testing), 133 and 167-68 (opining about finite element analysis of Bard's filters), and 135-138 (opining about how fracture of filters can impact forces and loads on the filter). Doc. 7296 at 13. Plaintiffs' response jumps over these paragraphs entirely, citing instead to paragraphs 59-77 and 141-182 of the report. Doc. 7812. As these ships pass in the night, the Court is left with little ability to reach specific conclusions.

It appears clear, however, that the doctors are not qualified to testify on technical matters such as those set forth in their report at paragraphs 115 (engineering and design implications related to cephalad angulation of hooks), 120 (gradient thresholds, safety margins, and "[c]ommon safety factors used in engineering,"), 127 (evaluation of specific fatigue resistance testing), 133 (opinion that engineers used too low a deflection), and 138 (opinion on improper balance struck in Recovery filter design). Doc. 7301. Drs. Roberts and Kalva have no training or experience on such matters, and Dr. Kinney's training and experience in this field are more than 30 years old. *See In re Ethicon Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2327, 2016 WL 4500765, at \*5 (S.D. W. Va. Aug. 26, 2016) ("Dr. Rosenzweig is not qualified to opine that Ethicon's testing was insufficient. There is no indication that Dr. Rosenzweig has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake."); *Morritt v. Stryker Corp.*, 973 F. Supp. 2d 177, 188 (E.D.N.Y. 2013) (physician's opinions about manufacturing defects in knee replacement components went "well beyond the

'reasonable confines' of his clinical expertise" even though he had significant clinical experience with the device).

Other somewhat technical opinions may be within the expertise of these doctors. They may be qualified, for example, to opine that filtering for blood clots is essentially a geometric issue, and that the loss of a filter arm or leg due to fracture results in larger gaps and places greater forces on the other arms and legs. Doc. 7301 ¶ 135. Or they may be qualified to explain that the changes to the Recovery filter are primarily dimensional, and opine as to what the changes suggest in terms of filter performance. *Id.* ¶ 156. Such opinions might reasonably be based on expertise and experience in implanting, monitoring, and removing IVC filters.

The Court cannot be more precise at this point. Although the Court generally concludes that Drs. Kinney, Kalva, and Roberts are not experts in mechanical design and testing, more specific rulings will have to be made during trial.

IT IS ORDERED that Defendants' motion to exclude expert opinions (Doc. 7296) is granted in part and denied in part as set forth in this order.

Dated this 22nd day of December, 2017.

David G. Campbell United States District Judge

Daniel G. Campbell